

**Pharmaceutical Management Branch  
Cancer Therapy Evaluation Program  
Division of Cancer Treatment, Diagnosis, and Centers  
National Cancer Institute**

**Policy and Guidelines for  
the Transfer of DCTDC Supplied Investigational Agents**

- DCTDC supplied investigational agents may be transferred, within an institution (intra-institutional transfer), from a completed DCTDC approved protocol to a DCTDC approved protocol that utilizes the same agent and formulation.
- An NCI Investigational Drug Transfer Form must be completed and submitted by fax (301- 402-0429) to the PMB for each agent transfer. Transfer forms should be submitted within 72 hours of the actual transfer. A copy should be retained for your records.
- Transfer of DCTDC supplied investigational agents from an active protocol requires prior PMB approval, (PMB should be notified the next working day if emergent transfers are required during weekends or holidays). Transfer of investigational agents from an active protocol should be restricted to the following situations: excessive inventory for a protocol; investigational agent has short dating; or medical emergency.
- Transfer of DCTDC supplied agents to non-DCTDC approved protocols is NOT permitted under DCTDC, NCI, and FDA policies and regulations.
- Transfer of DCTDC supplied agents for commercial use is both prohibited and illegal. Replacement of DCTDC supplied agents with commercial agents is also prohibited and illegal.
- Transfer of DCTDC supplied agents shall only be made between registered active NCI investigators.
- The “transferring” investigator must be the investigator who originally ordered the agent or the investigator to whom the agent was previously transferred (i.e., “double transfer”).
- The “receiving” investigator must be a participant on the trial to which the agent is being transferred.
- “Borrowing” of investigational agents is prohibited. All transfers must be documented. Investigational agents should NOT be ordered for one protocol to replace what was “borrowed” from another protocol.
- All DCTDC investigational agents shall be stored and accounted for separately by protocol. If an agent is used for more than one protocol, there should be separate physical storage and accountability for each protocol. PMB provides and accounts for agents on a protocol by protocol basis.
- Blinded studies -

- Agents for blinded studies should NEVER be transferred between protocols.
- Agents for blinded studies may be transferred between investigators with prior PMB approval.

*Questions or comments regarding investigational agent transfer should be addressed to the Pharmaceutical Management Branch by telephone (301-496-5725) or fax (301-402-0429).*

04/25/97